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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,100	11/18/2003	John L. Neumeyer	04843/118003	6112
21559	7590	02/13/2006	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			DESAI, RITA J	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/716,100

Applicant(s)

NEUMEYER ET AL.

Examiner

Rita J. Desai

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on IDs filed 1/23 and amendment filed 11/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,5-7,9,12-15 and 20-22 is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18 and 19 is/are rejected.
- 7) ☒ Claim(s) 1, 4, 8, 10, 11, 16 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/23/06</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-22 are pending . Claims 2, 3, 5-7,9, 12-15 and 17-22 are withdrawn.

Applicants had elected group II without traverse. Applicants should cancel the non-elected subject matter.

Response to the arguments for the 112 rejection:-

The arguments have been found to be persuasive. The John Neumeyer reference shows the various R' values encompassing the R definition of the applicants.

Applicants have not cancelled the non-elected subject matter.

The examiner has now rejoined the method of treating claims 17-19 limited to the scope of the elected group II.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. Applicant's claims are drawn to compounds that can treat any disorder associated any and all diseases due to dopamine dysregulation .. The specification defines in table I a few in vitro tests to test the DAMGO, NALTRINDOLE, and U69593 activity. The results obtained are also varied . Just for the 4 compounds 69-71 the results vary from .17 to 30 for μ K and δ K . The specification gives no guidance to one of ordinary skill in the art that any

Compound	K _i (nM) \pm SE			Selectivity	
	[³ H] DAMGO (μ)	[³ H]Naltrindole (δ)	[³ H]U69,593 (κ)	μ : κ	δ : κ
69	130 \pm 5.8	1100 \pm 30	29 \pm 1.4	4.5	38
70	1.10 \pm 0.13	190 \pm 9.7	6.4 \pm 0.53	0.17	30
71	1.5 \pm 0.21	29 \pm 2.0	0.049 \pm 0.0046	30	590
72	7.10 \pm 0.47	230 \pm 21	0.79 \pm 0.02	9.0	290

disorder can be treated.

The expression “diseases due to dopamine dysregulation.” does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. The functional language recited without any correlation does not meet the written description requirement for the expression “diseases due to dopamine dysregulation “ as one of ordinary skill in the art could not recognize or understand which diseases /disorders are treated by the mere recitation of the function. Claims employing functional language at the point of novelty, such as applicants', neither provide those elements required to practice the inventions, nor “inform the public” during the life of the patent of the limits of the monopoly asserted. The expression could encompass myriad of diseases and applicants claimed expression represents

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only an invitation to experiment regarding possible treatments. The diseases included can be ones that are still not discovered to be treatable by dopamine dysregulation.

Conclusion

The claims 18 and 19 are rejected.

Claims 1, 4, 8, 10, 11, 16 and 17, limited to the scope of the elected group II are found to be allowable and hence are objected to as containing non-elected subject matter.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

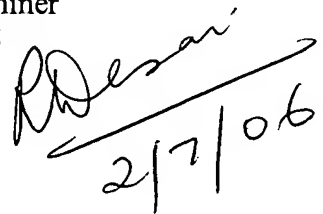
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai
Primary Examiner
Art Unit 1625

Handwritten signature of Rita J. Desai and the date 2/7/06.

R.D.
February 7, 2006